REMARKS

The present response is filed to address the comments in the Office Action mailed October 6, 2003. This response is timely filed in view of the concurrently filed Petition for One-Month Extension of Time and payment of the required fee.

Comments

The restriction requirement divided the present invention into 27 different groups of inventions. Further, the Office Action asserts that these groups do not relate to a single general inventive concept. Applicants respectfully traverse this restriction requirement and assert that the pending claims do indeed share the same or corresponding technical features.

At the outset, Applicants assert that the invention is not divisible into 27 different groups and find such division to be extremely burdensome on the Applicants. Applicants further assert that the present invention is related to a single general inventive concept. The invention is completely independent of the special way to detect analytes. It appears that the Examiner has divided the pending claims into 3 major groups: Groups I-IX concerning a method for detection of analytes in a sample; Groups X-XVIII concerning a support for detection of analytes in a sample; and, Groups XIX-XXVII drawn to methods of making the support for detection of analytes.

Applicants emphasize that the invention is completely independent of specific methods for detecting analytes. The Applicants respectfully point out to the Examiner that no such unity of invention problems were found in the International Stage of examination of the present application. In fact, a copy of the International Preliminary Examination Report, which is attached, indicates that there are no issues concerning unity of invention in the 27 claims filed in the international application and that all claims satisfied the patentability criteria of novelty, inventive step, and commercial applicability.

While Applicants understand that the findings of the International Preliminary Examining Authority are not conclusive or dispositive with regard to practice in the United States, Applicants respectfully assert that this report is in extreme contrast to the present restriction requirement which asserts that the invention can be divided into 27 different groups. The following paragraphs explain how the pending claims relate to a single general inventive concept and show how similar claims share the same or corresponding technical features.

The first aspect of the invention is outlined in Claim 1 annexed to the international

preliminary examination report. There is an optical transparent substrate provided with detection fields arranged along at least one spiral line or along a multitude of concentric circular lines. After contacting the sample with the detection fields, an optical reflector layer is applied to that side (front side) of the substrate which carries the detection fields thus covering the detection fields. In a subsequent measurement, detecting light incidenting from the back side of the substrate travels through the optical transparent substrate, then through the detection fields and the substrate to a respective detector. This optical measurement can be done by an ordinary CD-rom reading device.

The invention avoids the drawback of the prior art as outlined in the introductory part of the specification (acknowledgment of article "metal nano clusters as transducers for bioaffinity interactions"). Here the polycarbonate substrate is provided within a reflecting layer prior to the contact with the sample. Upon the reflecting layer (e.g. silver layer) a separation layer is applied which carries the detection fields. Then the sample is brought into contact with the detection fields. In the subsequent optical measurement light is hitting the polycarbonate disk from the front side, that is, first running through the detection fields, then through the separation layer to the optical reflection layer, and then back through the separation layer and the detection fields to the detector. The problem not solved until now is that application of the specific separation layer, which is able to immobilize the respective binders onto the reflection layer of the polycarbonate substrate, creates problems. Here, the thickness of the separation layer is a decisive parameter. The thickness must be chosen in a predetermined range which is dependent on the wavelength of the light irradiated during the subsequent evaluation. In particular, one must ensure that the separation layer has an exact even thickness throughout its entire extent. The present invention avoids this severe drawback in that the critical separation layer is no longer necessary.

The present invention is completely independent of the specific assay or beads used for the detection of analytes. It is only necessary that the result of the interaction between the analytes with the respective binders has an effect which can be detected by light.

The second aspect of the invention is claimed in Claim 23 annexed to the international preliminary examination report. Here, the interaction of the analytes with the binders must have a detectable magnetic effect. According to the invention a magnetic layer containing magnetic and/or magnetizable particles is flatly applied over the planar face of the substrate which carries the detection fields. This may be done prior to the formation of the detection fields or after the

formation of the detection fields. Subsequently, the sample is contacted with the detection fields. This magnetic layer has a weak magnetic effect in order not to disturb the magnetic effects of the interaction between the sample and the binders. The advantage of this magnetic layer is the possibility to record additional data on the substrate which can be read together with the detection fields (see page 17, last paragraph to page 18, first paragraph of the description as annexed to the international preliminary examination report).

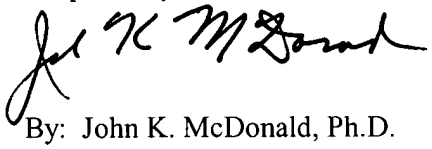
Applicants assert that the pending claims related to a single inventive concept and share the same or corresponding technical features. Applicants respectfully assert that the restriction requirement applied to the pending claims be reconsidered by the Examiner and a new restriction requirement be generated. Applicants believe that the arguments presented above, combined with the results obtained in the International phase of the application as provided by the European Patent Authority as International Preliminary Examination Authority, strongly support our assertion that the present invention is not divisible into 27 different groups of claims.

Nevertheless, in accordance with the requirements of U.S. Patent practice, Applicants assert that Groups I-IX represent a single group, and Applicants choose this single group for further prosecution. Within the 9 groups (I-IX) which Applicants assert should be one, Applicants agree to pursue Group I as outlined in the Office Action, namely Claims 28-58 drawn to a method for detection of analytes in the sample using a nucleic acid hybridization assay. Applicants again assert their argument that Groups I-IX are one group of inventions and are only providing the current election in accordance with 37 C.F.R. §1.499.

Conclusion

This response fully addresses the points outlined in the Office Action mailed October 6, 2003 and Applicants respectfully request reexamination of the claims and issuance of a new restriction requirement. Please do not hesitate to call the undersigned attorney at (404) 745-2470 if the Examiner would like to discuss this response further.

Respectfully submitted,



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PATENT COOPERATION TREATY

From the: AGENCY TASKED WITH THE INTERNATIONAL PRELIMINARY EXAMINATION

To:
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PRECHTEL BÖHM WEISS TIESMEYER HERZOG
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[stamp:]
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May 16, 2001
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NOTIFICATION CONCERNING THE TRANSMISSION OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(Rule 71.1 PCT)

File Number of the Applicant or Attorney: 19503P WO	Date Sent: (Day/Month/Year) 5/15/2001
	IMPORTANT NOTIFICATION

International Application Number	International Application Date (Day/Month/Year)	Priority Date (Day/Month/Year)
PCT/EP00/00876 -	2/3/2000	2/3/1999

Applicant: EUROPÄISCHES LABORATORIUM FÜR MOLEKULARBIOLOGIE et al.

1. The applicant is informed that the agency tasked with the international preliminary examination is transmitting herewith the international preliminary examination report developed for the international application with the relevant attachments if necessary.

2. A copy of the report, with the relevant attachments if necessary, is being transmitted to the International Bureau for further forwarding to all selected offices.

3. On request of a selected office, the International Bureau will prepare a translation of the report (but not the attachments) into English and transmit it to the office.

4. REMINDER

   For entry into the national phase the applicant has to perform (Article 39 (1)) (see also the information transmitted in Form PCT/IB/301) certain transactions (filing of translations and payment of national fees) before each selected office within 30 months of the priority date (or still later in many offices).

   If a translation of the international application is to be transmitted to a selected office, then this translation must also contain a translation of all attachments to the international preliminary examination report. It is the responsibility of the applicant to prepare such translations and transmit them directly to the relevant offices.

   Further details concerning the authoritative deadlines and requirements of the selected offices are to be found in Volume II of the PCT guide for applicants.

Name and Address of the Agency Tasked with the International Examination	Authorized Official
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PATENT COOPERATION TREATY
PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(Article 36 and Rule 70 PCT)

File Number of the Applicant or Attorney	ADDITIONAL PROCESSING	see notification concerning the transmission of the international preliminary examination (Form PCT/IPEA/416)
19503 WO		

International Application Number	International Application Date (Day/Month/Year)	Priority Date (Day/Month/Year)
PCT/EP00/00876	2/3/2000	2/3/1999

International Patent Classification (IPC) or national classification and IPC
G01N33/543

Applicant
EUROPÄISCHES LABORATORIUM FÜR MOLEKULARBIOLOGIE et al..

1. This international preliminary examination report was developed by the agency tasked with the international preliminary examination and is being transmitted to the applicant pursuant to Article 36.

2. This REPORT includes 5 pages in all including this cover sheet.

☒ Furthermore, ATTACHMENTS accompany the report. They are pages with descriptions, claims, and/or drawings which were changed and are based on this report, and/or pages with corrections done before this agency (see Rule 70.16 and Section 607 of the Management Guidelines for the PCT).

These attachments include 35 pages in all.

3. This report contains specifications concerning the following points:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ No development of an opinion concerning novelty, inventive activity, and commercial applicability
- IV ☒ Insufficient unity of the invention
- V ☒ Substantiated finding according to Article 35(2) with regard to novelty, inventive activity, and commercial applicability; documents and explanations in support of this finding
- VI ☐ Certain cited documents
- VII ☐ Certain deficiencies in the international application
- VIII ☐ Certain notes concerning the international application

Date of Filing of the Application	Date of Completion of the Report
7/7/2000	5/15/2001
Name and Address of the Agency Tasked with the International Examination [logo] Europaisches Patentamt D-80296 München Tel. +49 89 2399 – 0 Tx: 523656 epmu d Fax: +49 89 2399 – 4465	Authorized Official [logo] Goetz, M. Tel. No. +49 89 2399 8697

INTERNATIONAL PRELIMINARY EXAMINATION REPORT **International File No.**: PCT/EP00/00876

I. Basis of the report

1. 1. With regard to the components of the international application (*Replacement pages that were submitted to the filing office in response to a request pursuant to Article 14 are considered "originally submitted" in the context of this report and are not appended to it, because they do not contain any amendments(Rules 70.16 and 70.17)*):

Specification, pages:

1-3, 3a-3b, 4-26	submitted on	March 23, 2001 with letter of March 23, 2001

Claims, No.:

1-27	submitted on	March 23, 2001 with letter of March 23, 2001

Drawings, sheets:

1/1	original version

2. With regard to the language: All the above-mentioned components were available to the authority in the language in which the international application had been submitted, or they were submitted in that language, unless information to the contrary is given under this point.
The components were available to the authority in the language, or were submitted in this language, namely

☐ the language of the translation, which was submitted for the purposes of the international search (pursuant to Rule 23.1 (b)).

☐ The publication language of the international application (pursuant to Rule 48.3 (b)).

☐ The language of the translation which was submitted for the purpose of the international preliminary examination (pursuant to Rule 55.2 and/or 55.3).

3. With regard to the nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence protocol which:

☐ is contained in writing in the international application.

☐ was submitted together with the international application in a computer readable form.

☐ was subsequently submitted to the authority in written form.

☐ was subsequently submitted to the authority in a computer readable form.

☐ The statement that the subsequently submitted written sequence protocol does not go beyond the disclosure content of the international application at the time of the application was submitted.

☐ The statement that the information recorded in computer readable form corresponds to the written sequence protocol was submitted.

4. Because of the amendments, the following documents have been removed:

☐ Specification Pages:

☐ Claims No.:

☐ Drawings Sheets:

5. ☐ This report was prepared without taking account of (some of) the amendments since, in the view of the agency, these go beyond the disclosure in the originally submittedversion, for the reasons stated (Rule 70.2(c)):

6. Any other remarks:

IV. Lack of unity of the invention

1. Upon the request to limit the claims or to pay additional fees, the applicant has:

☐ limited the claims.

☒ paid additional fees.

☐ paid additional fees with opposition.

☐ neither limited the claims nor paid additional fees.

2. ☐ The authority has noted that the requirement of unity of the invention has not been fulfilled, and pursuant to Rule 68.1 it has decided not to request that the applicant limit the claims or pay additional fees.

3. The authority is of the opinion that the requirement of unity of the invention according to Rules 13.1, 13.2 and 13.3

☒ has been met

☐ has not been met for the following reason:

4. Therefore, for the preparation of this report, an international preliminary examination was carried out for the following parts of the international application:

☒ all parts.

☐ the parts which pertain to Claims No.

V. Substantiated determination per Article 35(2) regarding novelty, inventive step and commercial applicability; documents and statements to support the determination

1. Determination

Novelty (N)	Yes: Claims 1-27 No: Claims
Inventive step(IS)	Yes: Claims 1-27 No: Claims
Commercial applicability (CA)	Yes: Claims 1-27 No: Claims

2. Documents and statements
see appendix

New Claims

1. Method for the detection of analytes in a sample, where analyte-specific binders (15) are immobilized in a multitude of detection fields (5, 7) located on one of the planar faces of a disk-shaped substrate (3), then the samples are contacted with the detection fields (5, 7), and subsequently the presence and/or the quantity of the analytes (17) to be detected is (are) determined by optical evaluation of the detection fields (5,7), where a substrate (3) prepared from an optically transparent material is used, in that the detection fields (5, 7) are arranged along at least one spiral line to (27) and/or a multitude of concentric circular lines on the substrate (3) characterized in that, after contacting the sample, an optical reflecting layer (21)-the planar face of the substrate (3) which carries the detection fields (5, 7)-is applied over the detection fields (5, 7).

2. Method according to Claim 1,
characterized in that the reflecting layer (21) is made of aluminum.

3. Method according to one of Claims 1 and 2,
characterized in that, with reference to the disk axis, radially adjacent detection fields (5, 7) are arranged with radial separation.

4. Method according to one of Claims 1-3,
characterized in that, along the spiral line (27) or a circular line, adjacent detection fields (5, 7) are arranged with separation from each other.

5. Method according to one of Claims 1-4,
characterized in that, on the planar face of the substrate (3), which carries the detection fields (5, 7) along the spiral line (27), or at least along one circular line, additional data fields (9) are formed which contain data pertaining to samples and/or detection fields and/or the evaluation.

6. Method according to Claim 5,
characterized in that detection fields (5, 7) and data field (9) are arranged alternately along the spiral line (27) or along at least one circular line.

7. Method according to Claim 5,
characterized in that detection fields and data fields are each formed on separate circular lines.

8. Method according to one of Claims 5-7,
characterized in that for the formation of the data fields (9), recesses (11) are formed in the planar face of the substrate (3) which carries the detection fields (5, 7) and in that the reflecting layer (21) is applied in such a manner that it reaches into the recesses (11).

9. Method according to one of Claims 5-7,
characterized in that for the formation of the data fields, a substance which influences incident reading light is applied on the planar face of the substrate which carries the detection fields.

10. Method according to one of Claims 1-9,

characterized in that, on the planar face of the substrate (3) which carriers the detection fields (5, 7), along the spiral line (27) or along at least one circular line, at least one reference field is formed, in addition, whose optical properties are used as reference in the evaluation of the detection fields (5, 7).

11. Method according to one of Claims 1-10,
characterized in that, after contacting the sample with the detection fields (5, 7), before the application of the reflecting layer (21), a coating layer (19) made of an optically transparent material is applied on the detection fields (5, 7).

12. Method according to Claim 11,
characterized in that for the coating layer (19) a polymer-based material is used.

13. Method according to one of Claims 1-12,
characterized in that a substrate (3) made of polycarbonate is used.

14. Method according to one of Claims 1-13,
characterized in that the substrate (3) is provided at a manufacturing site with binders (15), dried and packaged, and in that the substrate (3) so prepared is then brought to an application site which is at a distance from the manufacturing site, at which application site, the sample is contacted by a user with the detection fields (5, 7).

15. Method according to one of the preceding claims,
characterized in that the detection of the analytes is carried out by a detection of a change in the optical properties of the detection fields.

16. Method according to Claim 15,
characterized in that the optical change in the detection fields is caused by isotopes, enzymes, fluorochromes, dyes, metal colloids and/or beads.

17. Method according to Claim 16,
characterized in that latex beads, plastic beads, glass beads and/or metal beads are used.

18. Support for use with the method according to one of Claims 1-17,
comprising a disc-shaped substrate (3) made of an optically transparent material, to one of whose planar sites analyte-specific binders (15) are immobilized in a multitude of detection fields (5, 7), where the detection fields (5, 7) are arranged along at least one spiral line (27) and/or a multitude of concentric circular lines on the substrate (3), characterized by reflecting layer (21) being flatly applied, over the detection fields (5, 7), on the planar face of the substrate, which carries the detection fields, after contacting the sample with the detection fields (5, 7) characterized in that, for the formation of the detection fields and after contacting the sample with the detection fields, a magnetic layer, which contains magnetic and/or magnetizable particles, is flatly applied over each planar face of the substrate which carries detection fields.

19. Support according to Claim 18,

characterized in that a protective layer (25) is flatly applied on the reflecting layer (21).

20. Support according to Claim 19,
characterized in that the protective layer (25) is made of an acrylate-based material.

21. Support according to one of Claims 18-20,
characterized in that it is made available as a packaged commercial unit, prior to the application of the reflecting layer.

22. Support according to Claim 21,
characterized in that it is packaged in the dry state.

23. Method for the detection of analytes in a sample, in which analyte-specific binders are immobilized in a multitude of detection fields on at least one of the planar faces of a disc-shaped substrate, then the sample is contacted with the measurement fields, and subsequently the presence and/or the quantity of the analytes to be determined is (are) determined by evaluation of the detection fields, where the detection fields are magnetically evaluated and, for that purpose, binders, or the analytes to be detected, are labelled with magnetic and/or magnetizable labels and the detection fields are arranged along a multitude of concentric circular lines and/or along at least one spiral line on the substrate.

24. Method according to Claim 23,
characterized in that, after contacting the sample with the detection fields, a fixation layer is applied to the detection fields.

25. Method according to Claim 24,
characterized in that the fixation layer is flatly applied on each planar face of the substrate which carries detection fields.

26. Method according to Claim 24 or 25,
characterized in that, for the fixation layer, a polymer-based material is used.

27. Use of a support according to one of Claims 18-22 in an immunoassay and/or nucleic acid hybridization assay and/or lectin-sugar assay and/or protein-nucleic acid assay.